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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,199	12/21/2001	Claudio De Simone	2818-72	4379

23117 7590 06/09/2005

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EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 06/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,199

Applicant(s)

DE SIMONE, CLAUDIO

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/10/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 42-57 are presented for reconsideration on the merits.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 10, 2005, has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 42-57 are rendered vague and indefinite for the recitation of "potentially pathogenic bacteria" as recited in each of claims 42 and 43 at line 1. It is unclear what this means because the conditions a subject suffers from are caused by other pathogens besides bacteria, such as viruses and fungi. The inhibition of these pathogens is not clearly and distinctly set forth in the claims, in that such inhibiting of their growth is not positively claimed and set forth in the methods. Further, when is bacteria "potentially pathogenic" per se? These conditions for when bacteria are "potentially pathogenic" are not positively recited and set forth in the claims. The claims

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do not clearly and distinctly described the claimed methods. Thus, the metes and bounds of the claims can not be determined. In addition, it is unclear in claim 43, that component (b) is intended to be limited to DSM 11988 since the language "and optionally" reads on two additional bacteria which can be component (b).

Also the phrase "or mutant or derivatives thereof" as recited in claim 44 further renders claim 44 vague and indefinite because it is uncertain whether the mutants have all of the identifying characteristics of the strain and what constitutes a derivative of the strain? This language is suggested to be deleted.

Claim 51 is further rendered vague and indefinite in that it is unclear that all of the additional ingredients including "vitamins, quaternary ammonium bases, mineral salts, antioxidants, and anti-plaque agents" will be administered when treating all types of inflammatory conditions. Thus, these ingredients may not be administered when for example, vaginosis is being treated. Thus, it is not clear when these are administered in the claimed method and for which type of infectious or inflammatory conditions?

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 42-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavaliere Ved. Vesely et al. (US Patent No. 6,277,370), in view of Ehret (US Patent 6,159,724), these references cited of record, note page 3 of Office action of May 19, 2004 and also note prior action of November 30, and newly cited Tosi et al (US Patent

No. 5,176,911) newly cited Cavaliere Ved. Vesely et al. (US Patent No. 5,895,648)-also referred to as '648, newly cited Crapo et al (US Patent No. 5,747,026) and newly cited Persello (US Patent No. 5,286,478).

Claims have been newly amended and are drawn to methods of inhibiting growth of potentially pathogenic bacteria and optionally include *Lactobacillus brevis* strain DSM 11988.

Cavaliere Ved. Vesely et al (also referred to as Vesely) and Ehret cited and discussed of record, as noted above. Vesely teaches *Lactobacillus salivarius* which produces hydrogen peroxide that inhibits pathogenic bacteria, note column 3, lines 8-11. Ehret teaches *Lactobacillus brevis* utilizes arginine, see column 8, table 3, line 61.

Newly cited Tosi et al teach treating vaginosis infections with not only *Lactobacillus* (L) *casei*, L. *gasseri*, L. *crispatus* but also with L. *fermentum*, see column 1, lines 51-58.

'648 teaches probiotic which may contain beneficial ingredients such as vitamins, antioxidants, and mineral salts with the bacteria, note column 1, lines 45-50 and column 5, lines 40-55.

Crapo et al teach antioxidants for use in disease treatment, see abstract. Further, disclosed is an quarternary ammonium base at column 4, line 33 (i.e. tetraethylammoniumhydroxide).

Persello teaches antiplaque agents for use in dentrifice-compatible mineral salts. See column 1, lines 1 and 35, and column 2, line 29.

The claims differ from cited '370 patent in that the patent does not teach strain DSM 11988, but *Lactobacillus brevis* is disclosed as well as other *Lactobacillus gasseri* and *Lactobacillus casei*, and *Lactobacillus crispatus*, although a different strain thereof, ATCC 14869. Note column 6, lines 10, 13, 16 and 18, and further column 7, lines 57-58. Further, *L. fermentum* is not disclosed nor are specific beneficial ingredients as required in instant claim 51.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to select the combination of bacteria disclosed by Vesley and specifically for a strain of *L. brevis* capable of utilizing arginine as disclosed by Ehret or *L. fermentum* as disclosed by Tosi et al for inhibiting pathogenic bacteria. Further, the combination of bacteria are clearly disclosed by Vesely to be in effective amounts as set forth in each of instant claims 48 and 49, see column 2, lines 29 and 38 and column 4, lines 10, 11 and 13. Also the ratios would have been obvious as well based on these known amounts and a ratio of 1:1 is disclosed by Vesely at column 8, line 13.

Although DSM 11988 is not specifically disclosed it would have been obvious to select for other strains capable of utilizing arginine as such other strains are recognized by the cited prior art, note Ehret at table 3, line 61 of column 8. In addition, *L. gasseri* is not the only optional choice for component b and as evidenced by example 3 of the cited prior art the effective combination of non-producing and producing hydrogen peroxide strains of *Lactobacilli* for method of treating vaginitis is well known and taught by the cited prior art.

Also note the abstract of the cited prior art reference, Vessely-the primary reference and Tosi et al. One of skill would have expected successful results for the treatment of infectious vaginitis using composition comprising lactobacilli having these particular properties as claimed herein. The particular combination of *Lactobacillus salivarius* and *Lactobacillus brevis* strains is taught by the cited prior art.

Further, albeit the strain DSM 11988 is not disclosed by the cited prior art, but one of skill would have been motivated to select for different strain having similar properties thereof in order to provide for the combination as claimed. Clearly one of skill in the art would have expected successful results because the combination is taught by the reference wherein the only difference is that the strain is different but the selective property of the disclosed strain is not different.

One of skill in the art would be able to appreciate that the disclosed strain has the desired property and to select for another having this property is clearly an obvious modification of the cited prior art. Also to select for additional bacteria, such as *L. plantarum* is an obvious modification since Ehret clearly teaches *L. plantarum* at column 2, line 20 to be one of several additional lactobacilli. Therefore, the claims are rendered *prima facie* obvious over the cited references.

Also the additional ingredients of vitamins, quaternary ammonium bases, mineral salts, antioxidants and anti-plaque agents are disclosed in the prior art to be beneficial additive for treatment of infectious diseases. Thus, the use of these ingredients would have also been an obvious modification of the cited prior art as disclosed by Crapo et al, Persello and '648.

The claims are, therefore, rendered prima facie obvious over the cited art.

Response to Arguments

Applicant's arguments filed March 10, 2005, have been fully considered but they are not persuasive. The argument that strain DSM 11988 was disclosed in US Patent '854 is noted, however, the dates of the cited prior art are all before June 21, 1999 for which is Applicants' priority date.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah K. Ware
May 27, 2005



DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651